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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,221	08/20/2001	Paul Jarrett	0380-P02546USO	6745

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DANN DORFMAN HERRELL & SKILLMAN
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PHILADELPHIA, PA 19103-2307

EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 03/11/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/856,221	JARRETT ET AL.	
	Examiner	Art Unit	
	Dr. Kailash C. Srivastava	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on November 21, 2002(Paper Number 8).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3, 53- 58 and 63-68 is/are pending in the application.
- 4a) Of the above claim(s) 67 and 68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3, 53-58 and 63-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' Preliminary amendment filed August 20, 2001 as Paper Number 5 is acknowledged and entered.
2. Applicants' response and amendment filed November 21, 2002 as Paper Number 8 to Election requirement in Office Action mailed October 10, 2002 as paper Number 7 is acknowledged and entered.
3. Claims 63-68 have been added.
4. Claims 3 and 53-68 are presented for Examination

Restriction/Election

5. Applicants' election with traverse of Group III, Claims 3 and 53-58 filed November 21, 2002 as Paper Number 8 to Election requirement in Office Action mailed October 10, 2002 as paper Number 7 is acknowledged and entered.

The traversal is on the ground (s) that the instant application was filed under §371 and as such applicants are entitled to "a unity of invention standard" and a search of groups III-IV together would not place an additional burden on the examiner. This is not found persuasive because of the reasons of record under item 6 on pages 2-3, in Office Action mailed October 10, 2002 as paper Number 7. As pointed out in the citation referred to *supra*, there indeed are 4 different inventions because of their different classification and their recognized subject matter. Furthermore, the search for each of the distinct inventions of Groups III-IV is not co-extensive particularly with regard to the literature search. Further, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the condition for patentability is different in each case. Thus, it will be an undue burden to examine all of the inventive Groups in one application. In addition, a *prima facie* case for lack of unity was established in the aforementioned Office Action mailed October 10, 2002 as paper Number 7. Furthermore, a "correspondance" between nucleic acids and polypeptide, even if it were exact as argued (which it is not because of comprising language) is not a special technical feature shared between the two groups. Sharing elements in common does not make a special technical feature. Further the actions of another Office or even another examiner are

not binding. Therefore, the restriction requirement is still deemed proper and is made FINAL.

Newly submitted claims 67-68 are directed to an invention that is independent or distinct from the elected claims for the following reasons: Claims 67-68 are drawn to a different composition than that claimed in Claims 3 and 53-58. Moreover, Claims 67-68 recite subject matter that relates to an agent that encodes a pesticide material obtained from *Bacillus thuringiensis*. Accordingly, Claims 67-68 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

6. Claims 3, 53-58 and 63-66 are examined on merits.

Information Disclosure Statement

7. Applicants' Information Disclosure (i.e., IDS) filed August 20, 2001 as paper number 3 has been made of record and considered.

Priority

8. Applicants' claim for foreign priority under 35 U.S.C. 119 (a-d) is acknowledged.

Objection To Specification

9. The specification is objected to because the sequence identification numbers recited at Page 5, Line 38 to Page 6, Line 1 are not identified according to art-accepted sequence identification numbers (e.g., SEQ ID NOS: XX). Appropriate correction is requested. Applicants are cautioned to ensure that no new matter is added while the appropriate correction is made to the specification.

It is requested that the first line of the first page of the specification indicate that the instant application is a 371 of the earlier filed PCT application, as follows.

This application is a 371 of PCT/____/_____, filed _____, which claims priority to _____ application Serial No. _____, filed _____.

Claims Objection

10. Claim 3 is objected to for being in improper form because of abbreviations X. and B. Abbreviations in the first instance of claims should be expanded upon with the abbreviation

indicated in parentheses. The abbreviations can be used thereafter. Appropriate correction is required.

Claims 63-64 and 66 are objected to because the nucleotide sequence identification numbers recited in those claims are not identified according to art-accepted sequence identification numbers (e.g., SEQ ID NOS: XX). Appropriate correction is requested.

Claim Rejections - 35 U.S.C. § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 3, 53-58 and 63-66 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with those claims. The claims are directed to a proteinaceous (i.e., protein/polypeptide) material that strains of *Xenorhabdus bovienii* produce and the said material is referred to as a pesticidal agent (e.g., in Claims 3, 53-58 and 63-66), toxins (See Claims 57-58) or insecticidal toxins (see Claim 65). The said pesticidal agent also possesses the synergistic insecticidal activity as an oral insecticide with *Bacillus thuringiensis* cells.

From the record of the present written disclosure, the specification, while enabling for oral insecticidal activity against one or some species of insect of the order Coleoptera, Homoptera or Lepidoptera of a pesticidal agent obtained from two strains of *Xenorhabdus bovienii* and said agent having synergistic activity with *Bacillus thuringiensis* cells does not reasonably provide the said insecticidal activity of the said pesticidal agent from any, or all strains of *Xenorhabdus bovienii* (See Specification Page 3, Lines 23 to Page 4, Line 1). Furthermore, the examples in the specification demonstrate the pesticidal activity of the pesticidal agent from *Xenorhabdus bovienii* strains to only a few insects (See for e.g., specification Page 25, Line 25 to Page 27, Line 9 and Page 28, Line 25 to Page 30, Line 15) and the synergistic insecticidal activity of the said pesticidal agent from *Xenorhabdus bovienii* with *Bacillus thuringiensis* cells against only *Pieris brassicae*. Thus, the specification does not enable any person skilled in the art to which it pertains, or with which it is most

nearly connected to extrapolate the claimed invention to either any and all strains of *Xenorhabdus bovienii*, or all insects belonging to orders Coleoptera, Homoptera or Lepidoptera. In any case, orders Coleoptera, Homoptera or Lepidoptera are sufficiently large insect orders with a number of divergent members, and in the absence of demonstrated evidence of record that the said pesticidal agent crosses the spectrum of all/majority of insects in insect orders cited *supra*, the claimed invention is not considered enabled.

Furthermore, from the record of the present written disclosure, claims 64-66 are also non-enabling for the scope of the claims. The phrase "70% or more sequence identity" in claim 64 is not enabling. Applicants have not disclosed where changes to the sequence can be made as claimed and still retain an active functional toxic protein, because it is not clear from the claims if the changes in the nucleotide sequence are allowed to change the polypeptide sequence? If the changes in the polynucleotide results in changes in the polypeptide, then Claims 64-66 are clearly non-enabled because it is not clearly supported in the specification how changes in the sequence by addition, deletion, substitution or insertion of amino acid residues will **not** change the structure and functionality of the polypeptide or the insecticidal toxin and therefore of the pesticidal agent since from the current disclosure as presented the polypeptides are the pesticidal agent.

An ordinary artisan would not be able to practice the invention because undue experimentation will be required to obtain the pesticidal activity cited *supra* due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

13. Claims 3,53-58 and 63-66 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are directed to strains of *Xenorhabdus bovienii* that produce a pesticidal agent, the said pesticidal agent acts synergistically as an oral insecticide with *Bacillus thuringiensis* cells.

From the record of the present written disclosure, the two *Xenorhabdus bovienii* strains (NCIMB 40985 and NCIMB 40986) are essential to the invention recited in those claims. Those organisms must therefore be obtainable by a repeatable method set forth in

the specification or otherwise be readily available to the public. The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention, failing to provide an enabling disclosure and failing to present the best mode contemplated by applicant for carrying out the invention without complete evidence either that the claimed biological materials are known and readily available to the public or complete evidence of the deposit of the biological material.

Since a deposit for the two *Xenorhabdus bovienii* strains (NCIMB 40985 and NCIMB 40986) has been made under the terms of the Budapest Treaty, an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his/her signature, and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 C.F.R. § 1.808.

14. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

15. Claims 57-58 and 63-66 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- o The phrase "H toxin or I toxin" in claims 57-58 renders those claims indefinite because it is not clear what is meant by the phrase "H toxin or I toxin". The metes and bounds for the said phrase are not defined. Applicants should clarify the phrase "H toxin or I toxin".
- o Claims 57 and 58 each recite the limitation "H toxin or I toxin". There is insufficient antecedent basis for this limitation in the cited claim, because Claim 53 from which Claim 57 depends and Claim 55 from which Claim 58 depends does not cite "H toxin or I toxin".
- o Claim 65 recites the limitations "insecticidal toxin" and "bacterial nematode-symbiont". There is insufficient antecedent basis for this limitation in the cited claim, because neither Claim 54 from which Claim 65 depends, nor Claim 3

from which Claim 64 depends cite the limitations "insecticidal toxin" and "bacterial nematode-symbiont".

- o The recitation, "derivative" in claim 66 is unclear as well as confusing, and therefore indefinite because the term does not clearly define as to how similar a compound/composition/matter should be of the base compound/composition/matter to be called derivative, i.e. the term does not define the metes and bounds of the claimed subject matter. Appropriate correction/ clarification is requested.

All claims that depend directly from the rejected claims are also rejected under 35 U.S.C. §112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102/103

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

19. Claims 3, 53-58 and 63-66 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Jarrett et al. (WO 98/08388) in light of International J. Systematic Bacteriology (Volume 43, Page 864-865, 1993) and Ensign et al (WO 98/50427).

Claims recite a pesticidal agent (i.e., polypeptide/protein/ toxins) obtained from Xenorhabdus bovienii strains, said agent having oral insecticidal activity against insects of the order Coleoptera, Homoptera or Lepidoptera and said agent having synergistic oral insecticidal activity with Bacillus thuringiensis cells. The said agent is heat stable to 50°C.

Jarrett et al. (WO 98/08388) disclose a pesticidal/larvicidal/insecticidal activity of either cells or proteinaceous material obtained from culture supernatants from different *Xenorhabdus* spp./strains against members of two different insect orders when the materials cited *supra* are orally fed to larvae from the said two different Orders of insects (page 5, Lines 1-2 and 20-30; Page 15, Lines 10-17; Page 16, Lines 8-17 and Page 26, Lines 23-29). The said *Xenorhabdus* strains are *Xenorhabdus nematophilus* (Page 26, Lines 23-29) and the said insect orders are: Coleoptera and Lepidoptera. Furthermore, the said agent has pesticidal activity against the same insects that are recited in the instant invention, is a proteinaceous material stable up to the temperature of 55°C (Page 3, Line 36 to Page 5, Line 2; Page 27, Line 33 to Page 28, Line 1) and demonstrates synergistic insecticidal activity with *Bacillus thuringiensis* cells against *Pieris brassicae* (Page 18, Lines 18-20). Please note that *Xenorhabdus nematophilus* is the synonym for *Xenorhabdus bovienii* (see International J. Systematic Bacteriology, 1993, Volume 43, Page 864, Lines 52-55, 1993) and the genus *Xenorhabdus* is currently comprised of four recognized species, including *Xenorhabdus bovienii* and *Xenorhabdus nematophilus* (Page 5, Line 21 to Page 6, Line 9). Furthermore, the isolated protein/polypeptide/toxins from those species have pesticidal activities against insect orders Coleoptera and Lepidoptera (See Ensign et al. Page 2, Lines 3240; Page 5, Line 23; Page 6, Lines 3-5; Page 7, Lines 24-39; Page 9, Lines 21-30 and Page 10, Lines 5-17). Please also note that the composition (i.e., toxins having pesticidal activities) disclosed in Jarrett et al. (WO 98/08388) has the same properties and functional activity, i.e. the prior art toxins obtained from two different strains of *Xenorhabdus nematophilus* exhibit the same inactivity as instantly claimed. Thus, the Examiner cited prior art inherently must function as instantly claimed because the same composition from the same organisms is being assayed/applied in the same way to control same insect pests. Thus, Jarrett et al. inherently disclose insecticidal toxins (i.e., pesticidal agent) from *Xenorhabdus bovienii* having pesticidal activities against at least two insect Orders and said agent has synergistic pesticidal activity with *Bacillus thuringiensis* cells.

However, even if the reference strains as well as the pesticidal agent (i.e., toxins) obtained therefrom and the claimed strains and the pesticidal agent (i.e., toxins) obtained

from the claimed strains are not one and the same, and there is, in fact, no anticipation, the reference strain and compositions obtained would, nevertheless, have rendered the claimed *Xenorhabdus bovienni* and the pesticidal agent obtained therefrom *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made because the reference discloses members of the same Genus and species and the agent obtained therefrom through same steps and having same functional properties toward the members of same insect orders (i.e., Coleoptera, Homoptera or Lepidoptera) as recited in the instantly claimed invention.

Thus, the claimed invention as a whole was clearly *prima facie* obvious especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Please note that International J. Systematic Bacteriology and Ensign et al. are cited to establish inherent properties of the composition, not as prior art references

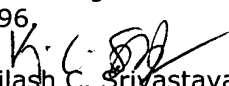
Conclusion.

20. No Claims are allowed.

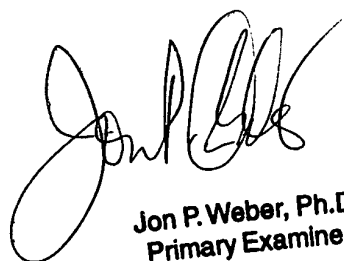
21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (703) 605-1196. The examiner can normally be reached on Monday-Thursday from 7:30 A.M. to 6:00 P. M. (Eastern Standard Time or Eastern Daylight Saving Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743 Monday through Thursday. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


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March 10, 2003


Jon P. Weber, Ph.D.
Primary Examiner